Celldex Announces Initiation of CDX-0159 Subcutaneous Formulation Study

September 13, 2021

HAMPTON, N.J., Sept. 13, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first cohort has been dosed in the Phase 1 study of the subcutaneous formulation of CDX-0159 in healthy volunteers. CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. The Company intends to utilize the subcutaneous formulation of CDX-0159 in its Phase 2 program in chronic urticarias, planned for initiation in the first half of 2022. Celldex is currently studying an intravenous formulation of CDX-0159 in Phase 1 studies in chronic spontaneous and chronic inducible urticarias and will initiate a third intravenous study in prurigo nodularis later this year.

“We believe CDX-0159 has significant potential to help patients in need across numerous diseases with mast cell involvement,” said Diane C. Young, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. “Advancing the development of the subcutaneous formulation is an important milestone for the CDX-0159 program that will support the initiation of later stage studies next year.”

The randomized, double-blind, placebo-controlled Phase 1 study will evaluate single ascending doses of CDX-0159 administered subcutaneously in healthy volunteers. Thirty two subjects will be enrolled across four dosing cohorts (50 mg, 150 mg, 300 mg and 600 mg) with 8 subjects in each cohort (6 active; 2 placebo). Subjects will be followed for 12-weeks after dosing. The primary endpoints of the study are safety and tolerability; secondary endpoints include pharmacokinetics, pharmacodynamics (circulating tryptase and stem cell factor) and immunogenicity. For additional information on this trial (NCT05031624), please visit www.clinicaltrials.gov.

About CDX-0159
CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT with high specificity and potently inhibits its activity. KIT is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells. In certain inflammatory diseases, such as chronic urticaria, mast cell activation plays a central role in the onset and progression of the disease.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer. Visit www.celldex.com.

Forward Looking Statement
This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct or that those goals will be achieved, and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to successfully complete research and further development and commercialization of Company drug candidates, including CDX-0159, in current or future indications; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; our ability to continue to obtain capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we have initiated or plan to initiate; and other factors listed under "Risk Factors" in our annual report on Form 10-K and quarterly reports on Form 10-Q.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Company Contact
Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
(508) 864-8337
scavanaugh@celldex.com

Patrick Till
Senior Director, Investor Relations & Corporate Communications
(484) 788-8560
ptill@celldex.com

Source: Celldex Therapeutics, Inc.